

# **AKYNZEO®**

Netupitant (ne-TU-pi-tant) 300mg and Palonosetron (pa-lo-NOS-etron) 500 microgram capsules

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## **Consumer Medicine Information**

### **What is in this leaflet**

This leaflet answers some common questions about Akynzeo. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits they expect it will have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet.**

You may need to read it again.

### **What Akynzeo is used for**

This medicine is used to prevent nausea (feeling sick) and vomiting caused by cancer chemotherapy in adult patients.

It is a combination medicine which contains two active ingredients. The active ingredients are called netupitant and palonosetron.

Netupitant belongs to a group of medicines called 'neurokinin-1 (NK1) receptor antagonists'.

Palonosetron belongs to a group of medicines called 'serotonin (5-HT3) receptor antagonists'.

Akynzeo works by blocking the actions of substances in your body and brain that are thought to cause nausea and vomiting.

**Ask your doctor if you have any questions about why this medicine has been prescribed for you.**

Your doctor may have prescribed it for another reason.

This medicine is not addictive.

This medicine is available only with a doctor's prescription.

There is not enough information to recommend its use in children under the age of 18 years.

## **Before you take it**

### **When you must not take it**

**Do not take this medicine if:**

- You are pregnant

- You are allergic to any medicine containing palonosetron or netupitant
- You are allergic to any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing or a tight feeling in your chest
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin

**Do not take Akynzeo if you have the rare hereditary problem of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency.**

**Do not take it after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.**

If it has expired or is damaged, return it to your pharmacist for disposal.

## **Before you start to take it**

Your doctor must know about all of the following before you are given this medicine.

**Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.**

**Tell your doctor if you have or have had any of the following medical conditions:**

- constipation
- bowel obstruction
- alterations in heart rhythm also known as QT prolongation
- other heart problems
- taking any medicines that may induce an abnormal heart rhythm such as amiodarone, nifedipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone
- liver disease
- imbalance of certain minerals in your blood such as potassium and magnesium
- an intolerance to fructose
- peanut or soya allergy.

**Tell your doctor if you are pregnant or plan to become pregnant.**

Do not take Akynzeo if you are pregnant or if you are a woman of childbearing potential not using contraception. Your doctor can discuss with you the risks and benefits involved.

**Tell your doctor if you are breast-feeding or planning to breast-feed.**

Do not breast feed if you are taking Akynzeo. It is not known whether Akynzeo passes into breast milk.

**If you have not told your doctor about any of the above, tell him/her before you start taking Akynzeo.**

It is not recommended to take Akynzeo in the days following chemotherapy unless you are receiving another chemotherapy cycle.

## **Taking or being given other medicines**

**Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.**

Akynzeo can affect other medicines both during and after treatment. These include:

- dexamethasone, a steroid used for a variety of conditions
- certain cancer chemotherapy medicines such as docetaxel, etoposide or cyclophosphamide
- certain antibiotics such as erythromycin or moxifloxacin
- midazolam, used as a sedative and to relieve anxiety
- ketoconazole, used to treat fungal infections
- rifampin, an antibiotic used to treat tuberculosis and other infections

- heart medications such as amiodarone, quinidine and nifedipine
- medicines normally used to treat certain mental and emotional conditions (antipsychotics) such as haloperidol, chlorpromazine, quetiapine and thioridazine
- domperidone, a medicine normally used to treat nausea and vomiting, or certain other gastric problems
- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram
- SNRIs (serotonin noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine, duloxetine.

These medicines may be affected by Akynzeo or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

## **How to take it**

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**If you do not understand the instructions on the box, ask your doctor or pharmacist for help.**

## **How much to take**

The recommended dose is one capsule by mouth, one hour before you start your chemotherapy cycle.

## **How to take it**

**Swallow the capsule whole with a drink of water.**

**If you have trouble swallowing your capsule, tell your doctor.**

## **When to take it**

**Take Akynzeo approximately one hour prior to starting your chemotherapy cycle.**

**Take it with or without food.**

## **How long to take it**

Akynzeo is a single dose given only on the day of chemotherapy treatment.

It is not recommended to take Akynzeo in the days following chemotherapy unless you are receiving another chemotherapy cycle.

## **If you forget to take it**

**If you forget to take your capsule, contact your doctor for instructions.**

## **If you take too much (overdose)**

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Akynzeo.**

**Do this even if there are no signs of discomfort or poisoning.**

## **While you are taking it**

### **Things you must do**

**Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.**

**Tell your doctor if you feel the medicine is not helping to prevent the nausea and vomiting.**

**If the medicine starts to upset you, tell your doctor.**

### **Things you must not do**

**Do not give this medicine to anyone else, even if their symptoms seem similar to yours.**

**Do not take it to treat any other complaints unless your doctor tells you to.**

## **Things to be careful of**

**Be careful driving or operating machinery until you know how Akynzeo affects you.**

Akynzeo may induce dizziness, somnolence or fatigue in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Side effects**

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are taking Akynzeo.**

This medicine helps most people with control of nausea and vomiting associated with chemotherapy treatment, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

**Do not be alarmed by this list of possible side effects. You may not experience any of them.**

**Ask your doctor or pharmacist to answer any questions you may have.**

**Tell your doctor, nurse or pharmacist if you notice any of the following and they worry you:**

- headache
- constipation
- general weakness
- tiredness
- generally feeling unwell
- indigestion, heartburn, loss of appetite, bloating or stomach pain
- vomiting
- pain on urination

The above list includes the more common side effects of your medicine.

**Tell your doctor as soon as possible if you notice any of the following:**

- slow, fast or irregular heart beat
- severe stomach pain
- dizziness or feeling light headed

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

**Tell your doctor immediately or go to the accident and emergency at your nearest hospital if any of the following happen:**

- swelling of the mouth, face, lips, tongue or throat, which may cause difficulty breathing or swallowing
- raised, itchy rash on the skin

These may be signs of a serious allergic reaction. You may need urgent medical attention. These side effect are rare.

**Tell your doctor or pharmacist if you notice anything else that is making you feel unwell.**

Other side effects not listed above may also occur in some people.

## **Storage**

### **Storage**

**Keep the capsule in the blister pack until it is time to take it.**

If you take the capsule out of the blister it may not keep well.

**Keep your medicine in a cool dry place where the temperature stays below 30°C.**

**Do not store Akynzeo or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.**

Heat and dampness can destroy some medicines.

**Keep it where children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Disposal**

**Ask your pharmacist what to do with any medicine that is left over or if the expiry date has passed.**

## **Product description**

### **What it looks like**

The Akynzeo capsule is opaque with a white body and a caramel cap with "HE1" printed on the body.

Akynzeo capsules are supplied in an aluminium blister containing 1 capsule.

## **Ingredients**

Active ingredient:

Akynzeo 300/500 - 300 mg netupitant and 500 micrograms palonosetron (as the hydrochloride) per capsule.

Inactive ingredients

- microcrystalline cellulose
- sucrose laurate

- povidone
- croscarmellose sodium
- silicon dioxide
- sodium stearyl fumarate
- magnesium stearate
- glyceryl caprylate / caprate
- glycerol
- polyglyceryl-3-dioleate
- purified water
- butylated hydroxyanisole
- gelatin
- sorbitol special glycerin blend A-810
- titanium dioxide (E171)
- iron oxide yellow, iron oxide red (E172) and iron oxide black (E172)
- shellac
- propylene glycol (E1520)
- ammonium hydroxide (E527).

Each Akynzeo hard capsule contains 7 mg of sorbitol.

Akynzeo contains sucrose. It may contain traces of lecithin derived from soya.

Akynzeo does not contain gluten, tartrazine or any other azo dyes.

## **Supplier**

Akynzeo is supplied in Australia by:

Mundipharma Pty Limited

ABN 87 081 322 509

88 Phillip Street

Sydney NSW 2000

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